

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Pahl, <i>et al.</i>)	ATTORNEY DOCKET:	04266864
)		
SERIAL NO.:	10/828,650)	GROUP ART UNIT:	1624
)		
PATENT NO.:	7,381,729)	CONFIRMATION NO.:	4921
)		
FILED:	April 21, 2004)	EXAMINER:	Susanna Moore
)		
TITLE:	4-(4-TRANS-HYDROXYCYCLOHEXYL) AMINO-2-PHENYL-7H-PYRROLO [2,3D] PYRIMIDINE HYDROGEN MESYLATE, ITS POLYMORPHIC FORMS, AND METHODS FOR MAKING SAME			
DATE:	December 1, 2008			

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RENEWED REQUEST FOR RECONSIDERATION OF THE DECEMBER 7, 2007
APPLICATION FOR PATENT TERM ADJUSTMENT**

This Renewed Request for Reconsideration of the December 7, 2007 Application for Patent Term Adjustment (“Renewed Request for Reconsideration”) is being filed pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702-1.705, and in view of the following documents:

1. The March 31, 2008 Office of Petitions communication On Application for Patent Term Adjustment (“First Petition Decision”), attached; and
2. The September 30, 2008 Decision on Request for Reconsideration of Patent Term Adjustment (“Second Petition Decision”), attached;
3. The September 30, 2008 decision by the United States District Court for the District of Columbia in *Wyeth v. Dudas*, Civ. Action No. 1:07-cv-01492-JR, 2008 WL 4445642, attached.

This Request for Reconsideration seeks an additional 99 days of patent term adjustment in addition to the 534 days provided in the Issue Notification mailed on May 14, 2008.

The statement of facts supporting this Renewed Request for Reconsideration is set forth herein. In view of the facts and arguments below, Applicants respectfully request that the patent

term for United States Pat. No. 7,381,729 (“the ‘729 Patent”) be adjusted from 534 days to 633 days.

Pursuant to 37 C.F.R. § 1.7, this request is being timely filed on the first business day following the response period given in the Second Petition Decision. The fee set forth in 37 C.F.R. § 1.18(e) has previously been paid and Applicants submit that no further fee is required for this Renewed Request for Reconsideration. If any additional fees are deemed required as a result of this Renewed Request for Reconsideration, the USPTO is hereby authorized to charge such fees to Deposit Account No. 13-0019.

STATEMENT OF FACTS UNDER 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.705(b)(2) Applicants respectfully submit this Statement of Facts in support of their Renewed Request for Reconsideration of the December 7, 2007 Application for Patent Term Adjustment.

Applicants hereby request that an additional 99 days of patent term adjustment be granted in addition to the 534 days of patent term adjustment previously granted in the Issue Notification, for a total patent term adjustment of 633 days. The bases for this Adjustment are as follows: 477 days pursuant to 37 C.F.R. § 1.702(a)(1), an additional 57 days pursuant to § 1.702(a)(4) and an additional 99 days pursuant to § 1.703(b)(1). The 99 additional days requested are the number of days between April 22, 2007 (the day after three years from the application's filing date) and July 29, 2007 (the date just prior to the filing of the RCE on July 30, 2007). Applicants are entitled to this additional patent term adjustment pursuant to 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. §§ 1.702(b) and 1.703(b)(1).

A summary of the relevant dates is as follows:

Application filing date:	April 21, 2004
Application filing date + 14 months:	June 21, 2005
Date of first Office Action:	October 11, 2006
Filing date + 3 years:	April 21, 2007
RCE filing date:	July 30, 2007
Issue fee payment date:	December 7, 2007
Issue fee payment + 4 months:	April 7, 2008
'729 Patent issue date:	June 3, 2008

Patent Term Adjustment Pursuant to 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. § 1.702(a)

Under 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. § 1.702(a), Applicants are entitled to an adjustment of the term of the '729 patent of 534 days, which is the number of days attributable to PTO examination delay ("*A Delay*"). The *A Delay* period consists of a 477-day adjustment period under 37 C.F.R. § 1.703(a)(1), and a 57-day adjustment period under § 1.703(a)(6).

With respect to the 477-day adjustment period, 37 C.F.R. § 1.702(a)(1) states that at least one of either a notification under 35 U.S.C. § 132 or a Notice of Allowance will be mailed within 14 months after filing of the application. The current application was filed on April 21, 2004;

however, the first notification under 35 U.S.C. § 132 (“the first Office Action”) was not mailed until October 11, 2006. Thus, pursuant to § 1.703(a)(1), Applicants are entitled to a patent term adjustment for the period beginning on June 22, 2005 (14 months from the filing of the application) and October 11, 2006. This period of time is equal to 477 days and was correctly assessed by the USPTO in the Notice of Allowance.

With respect to the 57-day adjustment period, § 1.702(a)(4) states that a patent will issue within four months of the issue fee being paid. The issue fee for the ‘729 Patent was paid on December 7, 2007; however, the ‘729 Patent did not issue until June 3, 2008. Thus, pursuant to § 1.703(a)(6), Applicants are entitled to a patent term adjustment for the period beginning April 7, 2008 (four months after the date the issue fee was paid) and ending June 3, 2008 (the date the ‘729 Patent granted). This period of time is equal to 57 days and was also correctly assessed by the USPTO.

Therefore, pursuant to §§ 1.702(a)(1) and 1.702(a)(4) the ‘729 Patent is entitled to 534 days of patent term adjustment for PTO delays associated with the *A Delay* period. As we understand the patent term adjustment granted thus far, the USPTO has properly taken these delays into account.

Patent Term Adjustment Pursuant to 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b)

In addition to the *A Delay* discussed above, pursuant to 35 U.S.C § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), Plaintiff is also entitled to an additional adjustment of the term of the ‘729 patent of 99 days, which is the number of days attributable to the failure of the PTO to issue a patent within three years after the actual filing date of the application in the United States, not including any time following Applicants’ request for continued examination of the application (“*B Delay*”). Section 1.702(b) states that the term of a patent shall be adjusted if its issuance was delayed due to the failure of the USPTO to issue the patent within three years after filing of the application. However, § 1.702(b)(1) states that any time consumed by continued examination of the application (*i.e.*, resulting from the filing of an RCE) shall not be considered in the determination of delay in failing to issue the patent within three years. Thus, Applicants are entitled to an additional patent term adjustment under § 1.702(b) for any delay associated with the failure of the USPTO to issue the ‘729 patent within three years of filing, but not including any time following the filing of the RCE.

The present application was filed on April 21, 2004. An RCE was filed in the present application on July 30, 2007. Thus, pursuant to § 1.703(b), Applicants are entitled to a patent term adjustment of a period equal to the number of days between April 22, 2007 (the day after three years from the filing date of the application) and July 29, 2007 (the date just prior to the filing of the RCE). This period of time is equal to 99 days.

Therefore, pursuant to § 1.702(b) the ‘729 Patent is entitled to 99 days of patent term adjustment for PTO delays associated with the *B Delay* period.

Lack of Overlap Between the *A Delay* and *B Delay*

Under 37 C.F.R § 1.703(f), the total patent term adjustment is adjusted to account overlap between periods of delay. This section derives from 35 U.S.C. § 154(b)(2)(A), which states that “to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” The relevant adjustment periods and bases for such adjustments are summarized in the following table:

Adjustment Period	Days in Period	Delay	37 C.F.R.
June 22, 2005 to October 11, 2006	477	A	§§ 1.702(a)(1) and 1.703(a)(1)
April 8, 2008 to June 3, 2008	57	A	§§ 1.702(a)(4) and 1.703(a)(6)
April 22, 2007 to July 29, 2007	99	B	§§ 1.702(b) and 1.703(b)(1)
TOTAL 633 days			

For the ‘729 patent, none of the *A Delay* period overlaps with the *B Delay* period. Therefore, there is no period of overlap to be excluded from the determination of patent term adjustment for the ‘729 patent under 35 U.S.C. § 154(b)(2)(A). Accordingly, pursuant to § 1.703(f), the present patent is entitled to a total of 633 days of patent term adjustment, which is the sum of the period of *A Delay* (534 days) and the period of *B Delay* (99 days).

In contrast to Applicants’ assessment of the overlap period, however, the USPTO stated in the Second Petition Decision that:

in considering the overlap, the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i) – (iii), and not just the period beginning three years after the actual filing

date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).

However, the USPTO's interpretation of this statutory section is improper because it considers an application delayed under § 154(b)(1)(B) before it has *actually* been delayed. The USPTO's interpretation is inconsistent with § 154(b)(1)(B), which only applies "if the issue of original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added). According to the wording of the statute, *B Delay* begins when the PTO has failed to issue a patent within three years, not before.

In addition, the USPTO's interpretation of 35 U.S.C. § 154 has been rejected by the United States District Court for the District of Columbia. See *Wyeth v. Dudas*, Civ. Action No. 1:07-cv-01492-JR, 2008 WL 4445642 (D.D.C. Sept. 30, 2008). In *Wyeth*, the court stated that the USPTO's view that a period of "B delay" always overlaps with any periods of "A delay" for purposes of applying 35 U.S.C. § 154 (b)(2)(A) cannot be squared with the actual language of the statute. *Wyeth*, 2008 WL4445642 at *3-4. Instead, the court indicated that for purposes of 35 U.S.C. § 154(b)(2)(A), a period of delay due to the USPTO's failure to issue a patent within three years does not begin until *after* three years from the filing date of an application.

Therefore, according to both the plain wording of 35 U.S.C. § 154 and the *Wyeth* decision, the *B Delay* period in the present application started on April 22, 2007, and not before. In addition, the period subsequent to the filing of an RCE is not included in the three-year time frame specified in 35 U.S.C. § 154(b)(1)(B). See Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34284 at n.9 (June 21, 2004). Thus, the *B Delay* period ended on July 29, 2007.

Because none of the *A Delay* periods overlap with the *B Delay* period, there is no period of overlap to be excluded from the determination of patent term under 35 U.S.C. § 154(b)(2)(A). Therefore, Applicants respectfully request that the '729 Patent be awarded an additional 99 days of patent term adjustment pursuant to §§ 1.702(b) for the *B Delay* period in addition to the 534 days of patent term adjustment granted in the Issue Notification under §§ 1.702(a)(1) and (a)(4). Thus, pursuant to § 1.703(f), the present application is entitled to a total of 633 days of patent term adjustment.

Concluding Remarks

Pursuant to § 1.705(b)(2)(iii), Applicants submit that the '729 Patent is not subject to a terminal disclaimer.

Pursuant to § 1.705(b)(2)(iv)(B), Applicants submit that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the '729 Patent as set forth in § 1.704.

Applicants submit that in view of the foregoing, the present application is entitled to an additional 99 days of patent term adjustment in addition to the 534 days to which the Office has already determined the '729 Patent is entitled, for a total patent term adjustment of 633 days. If, in the opinion of the Office, a telephone conference would help expedite the present Application for Patent Term Adjustment, the Office is invited to call the undersigned attorney.

Respectfully submitted,

By: /Jamison E. Lynch/
Jamison E. Lynch
Reg. No. 41,168

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Dated: December 1, 2008



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OFFICE OF PETITIONS

In re Application of :
Pahl et al. :
Application No. 10/828,650 : ON APPLICATION FOR
Filed: April 21, 2004 : PATENT TERM ADJUSTMENT
Attorney Docket No. 04266864 :

This is in response to the APPLICATION FOR PATENT TERM ADJUSTMENT filed December 7, 2007. Applicants request that an additional 100 days of patent term adjustment be granted in addition to the 477 days provided in the Notice of Allowance mailed on September 10, 2007.

The instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date. A decision is being **held in abeyance** until after the actual patent date. Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.703(b).

(This is true even in this instance where a request for continued examination (RCE) was filed. The computer will not undertake the § 1.703(b) calculation until the actual date of issuance of the patent has been determined. Accordingly, it is still too soon to make a determination as to the correctness of any period of adjustment that will or will not be entered pursuant to § 1.703(b)).

Patentees are given TWO (2) MONTHS from the issue date of the patent to file a written request for reconsideration of the patent term adjustment for Office failure to issue the patent within 3 years. A copy of this decision should accompany the

request. Patentees may seek such consideration without payment of an additional fee. However, as to all other bases for seeking reconsideration of the patent term adjustment indicated in the patent, all requirements of § 1.705(d) must be met. Requests for reconsideration on other bases must be timely filed and must include payment of the required fee.

Rather than file the request for reconsideration of Patent Term Adjustment at the time of the mailing of the notice of allowance, applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term pursuant to 37 CFR 1.705(d). The USPTO notes that it does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent and accordingly, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.

It is acknowledged that applicants are correct that any period of adjustment will be entered in light of 35 U.S.C. 154(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY, which provides that

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including -

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

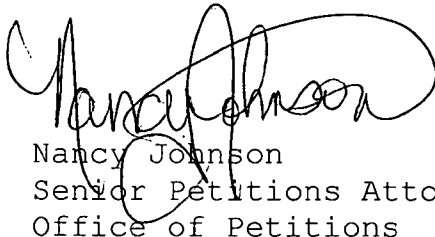
It is noted that a Request for Continued Examination (RCE) was filed in this application on July 30, 2007.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Office of Patent Publication for issuance of the patent. The patent term adjustment indicated on the patent (as shown on the Issue Notification mailed about three weeks prior to patent issuance)

will include any additional adjustment accrued both for Office delay in issuing the patent more than four months after payment of the issue fee and satisfaction of all outstanding requirements, and for the Office taking in excess of three years to issue the patent (to the extent that the three-year period does not overlap with periods already accorded).

Telephone inquiries specific to this decision should be directed to the undersigned at (571) 272-3219.

A handwritten signature in black ink, appearing to read "Nancy Johnson", with a large, sweeping loop at the end.

Nancy Johnson
Senior Petitions Attorney
Office of Petitions



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OFFICE OF PETITIONS

In re Patent No. 7,381,729	:	
Pahl et al.	:	DECISION ON REQUEST
Issue Date: June 3, 2008	:	FOR
Application No. 10/828,650	:	RECONSIDERATION OF
Filed: April 21, 2004	:	PATENT TERM ADJUSTMENT
Attorney Docket No. 04266864	:	

This is a decision on the "REQUEST FOR RECONSIDERATION OF THE DECEMBER 7, 2007 APPLICATION FOR PATENT TERM ADJUSTMENT," filed June 25, 2008. Patentee requests that the patent term adjustment indicated on the face of the patent be corrected from five hundred thirty-four (534) days to six hundred thirty-four (634) days.

The request for reconsideration of the patent term adjustment indicated in the patent is **DISMISSED**.

Patentee is given **TWO (2) MONTHS** from the mailing date of this decision to respond. No extensions of time will be granted under § 1.136.

On June 3, 2008, the above-identified application matured into U.S. Patent No. 7,381,729, with a Patent Term Adjustment of 534 days. Prior to issuance of the patent, on December 7, 2007, patentee timely filed an application for patent term adjustment requesting that an additional 100 days of patent term be granted for the Office taking in excess of three years to issue the patent. By decision mailed March 31, 2008, patentee was advised that a decision on this issue was to be held in abeyance until after the actual patent date and upon filing of a request by patentee. Pursuant to that decision, patentee timely filed the

instant request. Patentee continues to request correction of the patent term adjustment to increase the patent term adjustment to 634 days on the basis that the patent issued more than 3 years and 100 days after the date on which the application was filed, and a request for continued examination (RCE) was filed in this application three years and 100 days after the date on which the application was filed.

Pursuant to 35 U.S.C. 154(B)(i), § 1.703(b)(1) provides, in pertinent part that:

the period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) ... and ending on the date a patent was issued, but not including the sum of the following periods:

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued;

Thus, the filing of a request for continued examination (RCE) cuts-off the applicants' ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment.

In this instance, a RCE was filed on July 30, 2007. Thus, the ability to accumulate additional patent term adjustment against the three-year pendency provision ended July 30, 2007. Accordingly, the period of adjustment under § 1.702(b) is 99 days, counting the number of days beginning on April 22, 2007, and ending on July 29, 2007 (July 30, 2007 to June 3, 2008 is 310 days).

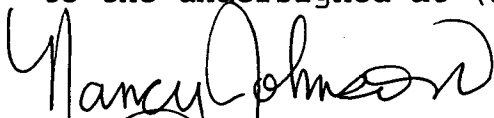
However, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap, with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. Further, in considering the overlap, the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii), and not just the period beginning three years after the actual filing date of the application, is the

period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). See 35 U.S.C. 154(b)(1)(B); 35 U.S.C. 154(b)(2)(A); and 37 CFR 1.703(f). In this instance, the period of delay of 99 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 477 days attributable to grounds specified in § 1.702(a)(1) and 57 days attributable to grounds specified in § 1.702(a)(4). Thus, no additional period of adjustment beyond the 534 (477 + 57) days was entered.

In view thereof, the patent term adjustment of 534 days indicated in the patent is correct

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) on application for patent term adjustment filed December 7, 2007. No additional fees are required.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3219.

A handwritten signature in black ink, appearing to read "Nancy Johnson", is written over the typed name and title.

Nancy Johnson
Senior Petitions Attorney
Office of Petitions

Only the Westlaw citation is currently available.

United States District Court, District of Columbia.

WYETH, et al., Plaintiffs,

v.

Jon W. **DUDAS**, Under Secretary of Commerce for Intellectual Property and Director of U.S. Patent and Trademark Office, Defendant.

Civil Action No. 07-1492 (JR).

Sept. 30, 2008.

Background: Patent owners brought action challenging method used by Patent and Trademark Office (PTO) to calculate extensions of patent terms for certain specified kinds of PTO delay.

Holding: The District Court, Robertson, J., held that extension of patent term based on PTO delay could exceed three years.

Ordered accordingly.

[1] Patents 291 ↪ 133

291 Patents

291VI Term

291k133 k. Extension. Most Cited Cases

Patent and Trademark Office's (PTO) interpretation of statute providing extensions of patent terms for certain specified kinds of PTO delay was not entitled to Chevron deference. 35 U.S.C.A. §§ 154(b)(2)(C)(iii), 154(b)(3)(A).

[2] Patents 291 ↪ 133

291 Patents

291VI Term

291k133 k. Extension. Most Cited Cases

Extension of patent term for any administrative delay by Patent and Trademark Office (PTO) in issuing patent more than three years after filing date did not necessarily overlap with extensions provided as result of PTO's failure to comply with enumerated statutory deadlines, and thus statutory prohibition against double-counting did not preclude patent applicants from claiming extensions in excess of three years. 35 U.S.C.A. § 154(b).

David O. Bickart, Kaye Scholer LLP, Washington, DC, Patricia A. Carson, Kaye Scholer LLP, New York, NY, for Plaintiffs.

Fred Elmore Haynes, U.S. Attorney's Office, Washington, DC, for Defendant.

MEMORANDUM OPINION

JAMES ROBERTSON, District Judge.

*1 Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years, 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain ... a grant ... for the term of seventeen years ... of the right to exclude others from making, using, or selling the invention throughout the United States...."). In 1994, in order to comply with

treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub.L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which—referred to as the Patent Term Guarantee Act of 1999—provided for the adjustments that are at issue in this case. Pub.L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called “A delays” or “A periods.” The second provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.^{FNI} See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the “B delay” or the “B period”. (“C delays,” delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

*2 The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.—To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is

manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for “periods of delay” to “overlap.”

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments,” has issued final rules and an “explanation” of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed.Reg. 34238. Here, the PTO “explained” that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), *the entire period during which the application was pending before the Office* (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, *is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A)*.

69 Fed.Reg. 34238 (2004) (emphasis added). In short, the PTO’s view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for “A delay” or for “B delay,” whichever is larger, but never A + B.

In the plaintiffs’ submission, this interpretation does not square with the language of the statute. They argue that the “A period” and “B period” overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are

two “A periods,” each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the “B period” begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first “A period” does not overlap the “B period,” because it occurs in 2003-04, not in 2005-07. The second “A period,” which covers 365 of the same days covered by the “B period,” does overlap. Thus, in plaintiff’s submission, this patent holder is entitled to four years of adjustment (one year of “A period” delay + three years of “B period” delay). But in the PTO’s view, since “the entire period during which the application was pending before the office” is considered to be “B period” for purposes of identifying “overlap,” the patent holder gets only three years of adjustment.

***Chevron* Deference**

***3** We must first decide whether the PTO’s interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). No, the plaintiffs argue, because, under the Supreme Court’s holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001), Congress has not “delegated authority to the agency generally to make rules carrying the force of law,” and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, citing *Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed.Cir.1996).

[1] Here, as in *Merck*, the authority of the PTO is limited to prescribing “regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.” 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a

comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO’s authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to “prescribe regulations establishing the *circumstances that constitute* a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application” (emphasis added)-that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO’s interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron*’s “step one,” without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT & T*, 512 U.S. 218, 229, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994) (“[A]n agency’s interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.”).

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under subsection (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

***4** [2] The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the

failure of the United States Patent and Trademark Office to issue a patent within 3 years.”(Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

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The PTO's interpretation appears to be driven by Congress's admonition that any term extension “not exceed the actual number of days the issuance of the patent was delayed,” and by the PTO's view that “A delays” during the first three years of an applications' pendency inevitably lead to “B delays” in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet and administrative deadline, and again because that failure has pushed back the entire processing of the application into the “B period.” Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that—again from the PTO's viewpoint—the applicant is not “compensated” for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context—as distinct from the legislative history—suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a “[g]uarantee of no more than 3-year application pendency,” 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable—they may even be consistent with Congress's intent—but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

FN1. Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b)(1)(b)(i)-(iii), as are periods attributable to the applicant's own delay. See 35 U.S.C. § 154(b)(2)(C).

D.D.C., 2008.

Wyeth v. Dudas

--- F.Supp.2d ----, 2008 WL 4445642 (D.D.C.)